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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,491	02/05/2002	Philip Kusk	8969-029	4096
21874	7590	12/05/2005	EXAMINER	
EDWARDS & ANGELL, LLP			SWITZER, JULIET CAROLINE	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1634

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/889,491

Applicant(s)

KUSK, PHILIP

Examiner

Juliet C. Switzer

Art Unit

1634

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 10 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 10 November 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): 112 2<sup>nd</sup> rejections.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 25 and 31.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 26-30 and 32-37.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

Continuation of 11. does NOT place the application in condition for allowance because: First it is noted that claim 31 was not rejected in the previous office action. This claim depends directly from claim 25, and is allowable as it is written.

The 112 2<sup>nd</sup> rejections of record are overcome by the amendment filed 11/10/05.

Applicant traverses the rejections under 112 1<sup>st</sup> paragraph.

Regarding the MGP polymorphism as a valid predictor of the rate of bone loss, applicants argue that the examiner has underrated the significance of the data presented. Applicant argues that the data presented in the specification demonstrates a sufficient difference in rate of bone loss for a physician to make a suggestion to a patient based on genotype at this polymorphism, and that the overlap of standard deviation does not imply that there is no significant difference between the groups. However, the examiner maintains, as thoroughly discussed in the rejection that in view of the highly unpredictable nature of this invention that the data are not sufficient to draw to conclusions set forth in the claims. Applicant argues that the two groups are "well separated" at 12 and 18 years from study beginning. "Well separated" is entirely subjective. It is noted that the figure is not drawn to any scale, with the difference between 1977 and 1979 (2 years) being the same as the difference between 1989 and 1995 (6 years). Drawn to scale, the lines might even "appear" closer together. This is why statistical analysis is necessary for evaluating whether the differences between populations are actually present or are due to normal variation in populations. Applicant points to page 32, lines 4 to 19, to support the position that the data are sufficient to support the claims. This portion of the specification states "None of the identified polymorphisms appeared to have a statistically significant impact on the change in bone mass over time." The rejection is maintained.

The arguments regarding OPN T1825C are similar to those presented for MGP and are not persuasive for similar reasons.

Applicant states that claim 27 requires that OPN T1825 should be measured with the BSP polymorphism and this is clearly demonstrated in figure 9. Again, there is no statistical analysis of the data. Further, claim 27 also requires a relationship between a polymorphism at base pair 520 and rate of bone mass loss. Thus, the claim is not commensurate in scope with the arguments.

Applicant argues that the examiner's comments regarding the unpredictability of the art are irrelevant in view of the data in the specification. However, the examiner feels they are relevant to establish that this art area is highly unpredictable. In the instant case this is coupled with questionable showings in the specification which are not supported with statistical analysis demonstrating likely differences between populations.

Applicant's comments regarding the quantity of experimentation factor are correct. The examiner regrets this error. The practice of the claimed invention would, however, require extensive experimentation to confirm that the suggested relationships exist, since the data in the specification do not appear to provide statistically relevant associations.

The rejection is maintained.

  
**JULIET C. SWITZER**  
**PRIMARY EXAMINER**